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EXAMINER	
LI, B	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/202,035	GORMAN, JEFFREY JOHN	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,19-20, 22, 24, and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,19,20,22,24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Preliminary amendment

Preliminary amendment filed in paper No. 17, 01/03/2001 are entered. Claims 1, 7, 14-15, 19-20, 22 and 24 are amended. Claims 1-33 are pending.

Election/Restrictions

Applicant's election with traverse of Claims 1-15, 19-20, 22, 24 and 26 of Group I that is further directed to the elected species of SEQ ID. NO. 1 filed in paper No. 20 is acknowledged. The traversal is on the ground(s) that (1) there is an unity of Invention of group I and Group II because they are related by "special technical feature", and (2) all of the sequences in claim 5 (SEQ ID Nos. 1-18 are of same length and same amino acid at each position. This is not found persuasive because the following reasons: (1). The inventions of Groups I and II lack the same or corresponding special technical features since the special technical feature already be taught over the prior art as evidenced by Alkerlind-Stopner et al. (J. Virol. 1990, Vol. 64, No. 10 pp. 5143-5148). Alkerlind-Stopner et al. teaches a specific antigenic peptide of the G protein respiratory syncytial virus (RSV), wherein the amino acids residues contains 4 cysteine residues at the same position 173, 176, 183 and 186 with disulfide-bond. (2). The species listed in the claims 5 comprising different amino acids, e.g. the amino acid at the right end of the SEQ ID NO. 1 is K, whereas the amino acid at the same position in SEQ ID NO 3 is R. Therefore, they renders as structurally different products and produce different biological effects

The requirement is still deemed proper and is therefore made FINAL.

Hence claims 1-15, 19-20, 22, 24 and 26 directed to SEQ ID NO 1 is considered before the examiner. Applicant is reminded to cancel the on-elected claims 16-18, 21, 23, 25 and 27-33 to the non-elected group and to amend the claims to the scope of the claimed invention on the merit.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Claim Rejections - 35 USC § 112

Claims 1-15, 19-20, 22, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bonds of respiratory syncytial virus (RSV) are not defined. The claim is interpreted in light of the specification, however, since the RSV is a big family of viruses, which consists of many nonsegmented negative strand RNA viruses and each particular virus also, contains many strains or serotypes and they have significant diversity in their immunogenicity. The claim should point out which strain or serotype of RSV is intended in the said claim.

Further, the claims 1, 5 and 6 renders indefinite in that the recitation of " having" used here is an open language that lack the patenable weight for defining what the structure of the claimed compound is precisely. Still further, the claim is not clear for defining the homology of the sequence. Applicant is reminded that Identity, homology or sequence similarity can be calculated by a variety of different methods, whereby the calculated identity between two sequences will be quite different depending on the algorithm used for calculation. In addition, the calculation of "identity" is affected by variables such as the relative weight given to the sequence gaps versus mismatches, or whether conservative substitutions are weighted differently from non-conservative substitutions. Because applicant has referred to a structure having a homology with non-defined percentage of identities. Please clarify.

This rejection of claim 1 effects the dependent claims 2-15, 19-20, 22, 24 and 26.

Claim 2 is indefinite in that the metes and bonds of the recited "mutants and variants thereof" are not defined. The claim is interpreted in light of the specification, however, the specification fails to teach what the "mutants and variants thereof" are. Therefore, the claim is considered indefinite.

Claim 8 is vague in that the peptidomimetic compound is not defined. the claim is interpreted in light of the specification, however, the specification does not teach what is the definition of peptidomimetic compound. Please clarify what kind of the compound is the peptidomemetic compound in said claims?

Claim 14 is unclear in that the metes and bonds of "an acceptable carrier" are not defined. The claim is interpreted in light of the specification, however, the specification fails to teaches what "an acceptable carrier" is referred in the said claim. Please clarify.

Claims 19 and 20 are indefinite in that the meted and bones of the human RSV are not defined. The claim is interpreted in light of the specification, however, since the RSV is a big family of viruses, which consists of many nonsegmented negative strand RNA viruses and each particular virus also, contains many serotypes. The claim should point out which RSV is intended in the said claim.

Claims 22, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are how to deliver the compound into the recipient animal and how to determine the protective immunity etc.

Claim 26 is recites the limitation "cell" in 24. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 14 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is draw to a diagnostic composition comprising a synthetic G protein peptide of RSV (amino acid sequence 149-197) with one or more individual amino acids replaced by an analogous structure.

The test of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and gain in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors include the following:

1). Unpredictability of the art. The field for diagnosis of RSV by peptide is unpredictable. This unpredictability is manifested at the practice level for the following aspect: (1) the affinity of the peptide biding to the diagnostic target of any or all RSV element is questionable because the specification only presents that the labeled peptide SEQ ID No. 1 only binds to one cell line Hep2 which is presumably to express the receptor of RSV; (2) the extracellular domain of the G protein has a high degree of strain-to-strain diversity (Fields Virology, line 5-6, col. 1, page 1321) and it has neither sequence nor structure homology with other family of RSV, such as paramyxovirus (lines 61-3, col. 1, US Paent No. 6,077,511), and (3) the impact of subgroup antigen variations of RSV is not completely clear (Fields, Virology, lines 1-8 page 1337). Therefore, the peptide of one stain of human RSV may only binds to its own strain of human RSV or having very limited application to other strains. For the diagnostic purpose, this highly strain restriction must be considered over a broad claimed utilization of a peptide without experimental approval.

2) State of the art. The prior art does not teaching any or all peptide with one or more amino acids replacement by an analogous structure can have similar antigenic or affinity to bind to the antibody or other viral particles. There are no demonstrated unambiguous successes for diagnostic RSV infection with any labeled peptide both in human and animal in clinical yet.

3) Number of working examples. Applicant presents no working examples of the claimed invention, e.g. (1) How to proceed diagnosis the RSV infection with the claimed peptide peptide in solid phase or in liquid phase? (2) What is the faults positive rate and faults negative rate by

using claimed peptide as diagnostic composition? (3) How to evaluate statically the significance of the diagnostic results by the claimed method etc.

4) Amount of guidance presented in the specification. The instant application only teaches that fluorescent labeled peptide can binds to the receptor or RSV. However, Applicant presents no guidance on how the skilled artisan would practice successfully diagnosis of RSV infection by using the claimed peptide compound.

5) Scope of the claims. The claims broadly read on a method for using the said peptide with one or more individual amino acids replaced by an analogous structure for diagnosis.

6) Nature of the invention. The invention involves a complicated and large quantity of serum samples' testing prospectively and retroprospectively. However, the specification fails to provide any of those kinds of tests.

7) Lever of the skill in the art. The level of the skill in the RSV diagnosis with peptide is high and significant hurdles remain to be overcome in order for the skilled artisan to practice successful gene therapy.

Given the above analysis of the factors which the courts have determined are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to have conducted undue and excessive experimentation in order to practice the claimed invention.

Claims 1-13, 15, 20, 22, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for synthesis of G protein peptide of SEQ ID NO. 1 of A2 strain of RSV and its corresponding D-amino acids replacement with or without labeling as well as using the said synthesized peptide (fluoresceinyl-149-197 or fluoresceinyl-163-197) to bind theHEp-2 cell and inhibit the cytopathic effect (cpe) of Hep-2 cells caused by A2 strain of human RSV infection in vitro, does not reasonably provide enablement for having a method for prevention or treatment of human RSV, such as Pneumovirus infection in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In the instant case, the specification teaches a method for making a synthetic peptide encoding by SEQ ID NO. 1 and a method for labeling the said compound. The specification also teaches that the flureseinyl-149-197 or fluoresceinyl-163-197 binds to RSV susceptible cells

HEp-2 and inhibit the cpe of the Hep2 cells caused by human RSV infection in vitro. However, the claimed invention broadly read on a pharmaceutical composition and a method for using the said composition comprising peptide SEC ID NO. 1 and any or all its derivatives to prevent or treatment of any or all human RSV infection, wherein the said derivatives is made by substitution of one or more amino acids with an analogous structure.

The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and gain in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors include the following:

1). Unpredictability of the art. The RSV infection and immunization art is extremely unpredictable. This unpredictability is manifested at every level from viral infection. (1) The nature of the antigenecity of RSV is unpredictable. (2) RSV G protein has a high degree of strain-to-strain diversity and serotype specificity, it means one peptide from one strain of RSV has very limited application. (3) RSV elicits an imperfect immune response in human is imperfect, that permit repeated infection in the life hood. (4) An enhanced disease in children is suspected to be caused by the vaccinated by RSV vaccine and the result of subunit vaccine made by F plus G protein of RSV is variable and in doubt for its safety etc. Applicants are directed to review the RSV vaccine development addressed by Hall (Science, Vol. 265, 1994, pp. 1393-1394).

2) State of the art. The art of using RSV vaccine at the time of application's invention was uncertain with no demonstrated unambiguous successes in treating or preventing the human RSV infection till the present.

3) Number of working examples. Applicants presents no working examples of the claimed invention, e.g. (1) Do any or all derivatives of the peptide based on SEQ ID No. 1 have same antigenic in vivo? (2) What kind of the immunity of the said peptide can be produced if any? does the said peptide produce any protective immunity to prevent human RSV infection? (3)

What kind the therapeutic benefit it can be produced? and (4) how the therapeutic benefit is evaluated in the patients or in a suitable animal model etc?

4) Amount of guidance presented in the specification. Applicants present no guidance on how the skilled artisan would practice successfully the peptide vaccine using the claimed peptide SEQ ID NO. 1 and its derivatives. Applicants present no guidance how the skilled artisan would address and overcome the art recognized problems associated with successful practicing of the vaccine or treatment in RSV.

5) Scope of the claims. The claims broad read on a pharmaceutical composition and a method for using the said pharmaceutical composition to prevent or treat human RSV infection, such as Pneumovirus infection, wherein the said composition consist of by a synthesized peptide compound SEQ ID No1 or any or it derivatives made by substitution any amino acid with one or more analogous structure.

6) Nature of the invention. the invention involves one of the most complex and unpredictable field of peptide vaccination and treatment.

7) Lever of the skill in the art. The level of the skill in the peptide vaccine and treatment of RSV is high; however, as noted by some of the preeminent researchers in RSV vaccine and treatment (i.e. Science 1994, Vol. 265, p. 1393-1394), important hurdles about which component would constitute the ideal vaccine remain to be overcome in order for the skilled artisan to practice successful RSV vaccine.

Nevertheless, the scope of the claims is directed to vaccine. However with regard to an unpredictable field, this does not constitute an adequate disclosure. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The result from in vitro experimentation can not extrapolated as a result in vivo. The applicant can not rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Hence, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the

claims, it is concluded that undue experimentation would be required to enable the intended claim.

Given the above analysis of the factors which the courts have determined are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to have conducted undue and excessive experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-6, 8, 10, 14-15, 19-20, 22, 24, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Langeijik et al. (US. Patent No. 6,077,551).

Langeijik et al. teaches a synthetic unglycosylated peptide comprising an amino acid sequence derived from protein G of a respiratory synsytial virus (both human RSV and bovine RSV), wherein said amino acid sequence preferable comprising at least the amino acid residues Nos 159-186, such as comprising the amino acid residue Nos. 157-193 of G protein. The some of the peptides have a sequence 100% similarity with claimed SEQ ID NO 1 (see Patent 551 SEQ ID NO 4, 8 and 12). The invention of 551 also teaches that the disclosed peptides or antigen or precursor thereof can be used for detecting or identifying the RSV types or subtypes, or antibodies against RSV types or subtypes by ELISA (see entire document, especially the col. 2, line 29 through col. 11, line 34) and for using as a vaccine composition to reduce or to inhibit the RSV infection in animal (see col. 11, lines 36-56). Although Patent 551 does not explicitly teaches that the Cysteine (Cys) 173 linked to Cys 186, and Cys 176 linked to Cys 182 by a disulfide-bond. However, this is inherited characteristics of Cys residue forming a disulfide-bond with nearby Cys residue by a natural occurring oxidation (see Chapter 5, Introduction to

proteins: The primary level of protein structure in Biochemistry Edited by Bowen et al. 1991, pp. 139). Therefore, the claimed invention is anticipated by the prior art.

(Applicant is reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products in term where the disulfide-bonds were formed in between the cysteine residues).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10, 14-15,19-20, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Alkerlind-Stopner et al. (J. Virol. 1990, Vol. 64, No. 10, pp. 5143-5148).

Alkerline-Stopner teaches et al. that a G protein peptide encoding the amino acids residue 134-198 of human RSV and several mutants that is about 16 amino acids long, wherein the basic sequence has 100% similarly with claimed SEQ ID NO. 1. The residue 191 D is an analogous of N in the same position of claimed SEQ ID NO. 1. The 4 cysteine residues are located at the same positions as claimed SEQ ID NO. 1 with a disulfide-bond linkage. Alkerline-Stopner et al. also teaches that said peptides were used for immunizing animals and for a diagnostic detecting the antibodies in infected animal or human by ELISA. Alkerline-Stopner further teaches that 3 Cys residues in the position of 176, 182 and 186 must be present in the peptide in order to keep the peptide complete affinity to the detect antibodies, whereas the Cys-173 can be deleted in the peptide compound. The disclosed peptide compounds are all synthetic peptidomimetic compounds that lack of glycosylation. Therefore, the claimed invention is anticipated by the recited prior art.

(Applicant is reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products in term where the disulfide-bonds were formed in between the cysteine residues).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15, 19-20, 22, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langeijik et al. (US. Patent No. 6,077,551) and Alkerlind-Stopner et al. (J. Virol. 1990, Vol. 64, No. 10, pp. 5143-5148) in further view of Guichard et al (PNAS, U.S. 1994, Vol. 91, p. 9765-9769).

The present invention is drawn to a G protein peptide of RSV, wherein the peptide is encode the amino acids sequence 158-196 residue of human RSV A2 N –terminal and its derivatives modified by substitution one or more individual amino acids with its analogous structure, such as corresponding D-amino acid. The said sequence is encoded by SEQ ID No. 1 and there are 4 Cys residues in the position 173, 176,182 and 186, wherein the Cys residues in between the 173 and 186 and 176 and 182 are linked with disulfide-bond. The said SEQ ID NO. 1 peptide can be labeled with detectable marker, such as radioactive material, biotinated material or fluoresced chemicals. The claimed peptide can be used as a pharmaceutical composition for diagnosis for prevention and treatment RSV infection as well as diagnosis.

Langeijik et al. teaches a synthetic unglycosylated peptide comprising an amino acid sequence derived from protein G of a respiratory synsytial virus (both human RSV and bovine RSV), wherein said amino acid sequence preferable comprising at least the amino acid residues Nos 159-186, such as comprising the amino acid residue Nos. 157-193 of G protein. The some of the peptides have a sequence 100% similarity with claimed SEQ ID NO 1 (see Patent 551 SEQ ID NO 4, 8 and 12). The invention of 551 also teaches that the disclosed peptides or antigen or precursor thereof can be used for detecting or identifying the RSV types or subtypes, or antibodies against RSV types or subtypes by ELISA (see entire document, especially the col. 2, line 29 through col. 11, line 34) and for using as a vaccine composition to reduce or to inhibit the RSV infection in animal (see col. 11, lines 36-56). Although Patent 551 does not explicitly

teaches that the Cysteine (Cys) 173 linked to Cys 186, and Cys 176 linked to Cys 182 by a disulfide-bond. However, this is inherited characteristics of Cys residue forming a disulfide-bond with nearby Cys residue by a natural occurring oxidation (see Chapter 5, Introduction to proteins: The primary level of protein structure in Biochemistry Edited by Bowen et al. 1991, pp. 139). Therefore, the claimed invention is anticipated by the prior art. Patent 551 differs in that the peptide is not substituted with its analogous structure, such as D-amino acid or labeled with any detectable marker. Patent 551 also does not teach that the one or more Cys residue can be deleted.

Alkerline-Stopner teaches et al. that a synthetic unglycosylated G protein peptide encoding the amino acids residue 134-198 of human RSV and several mutants that is about 16 amino acids long, wherein the basic sequence has 100% similarly with claimed SEQ ID NO. 1. The residue 191 D is an analogous of N in the same position of claimed SEQ ID NO. 1 and it also contains 4 Cys residues with a disulfide-bond linkage at the same positions of claimed SEQ ID NO. 1. Alkerline-Stoper et al. also teaches that said peptides were used for immunizing animals and for detecting the antibodies in infected animal or human by ELISA. Alkerline-Stopner's contribution over the prior art is that he demonstrated that the disulfide-bond in between the Cys residues, at least three cisterns in positions 176, 182 and 186 play critical role in maintenance of the ontogenetic activity of the protein G peptide (see page 5147, lines 3641 on the 2 col.). However, the test result indicates that the Cys-173 can be deleted in the peptide compound. Alkerline-Stopner does not teach et al. the compound peptide is replaced with its analogous structure, such as D-amino acid and the peptide compound is labeled with any detectable marker.

However, the nature L-amino acid replaced with its analogous D-amino acid in the peptide research field is well know in the art for the purpose for increasing the stability of the peptide but not impairing its immmunogenicity as evidenced by Guichard et al. (PNAS, U.S. 1994, Vol. 91, pp. 9765-9769, see entire document). The methods for labeling a well-known peptide with different detectable markers are just a design choices but not an unobvious discovery since the labeling methods are all well documented in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references of Langeijik et al. and Alkerlind-Stopner et al. in further

view of Guichard et al to make a protein G peptide of RSV which having the well known conserved antigenic sequence within the range disclosed by Langeijik et al. and/or Alkerlind-Stopner et al. with further modifying the peptide by substitution the L-amino acid with its D-amino acid as taught by Guichard et al. to induce the immune response in animal or to do the diagnostic ELISA assay by labeling the peptide with any detectable marker without unexpected results. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

June 15, 2001

JAMES HOUSEL 6/16/01
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600